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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,021	11/26/2003	Keith M. Orr	22956-239	7261

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EXAMINER
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DORNBUSCH, DIANNE

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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03/06/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/724,021	<b>Applicant(s)</b> ORR ET AL.	
	<b>Examiner</b> DIANNE DORNBUSCH	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/08/2004 and 01/03/2006</u> .                               | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim does not specify that the proximal end is of which of the two components.

The examiner will examine this as being the proximal end of the insertion tube.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6, 8-11, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dragan et al. (6,328,715).

Dragan discloses the following claimed limitations:

Claim 1: A device for arthroscopically delivering a tissue scaffold to a damaged or injured tissue site, comprising: a first component (28) having a flared proximal end (30), a distal end (Fig. 5), and an elongate, hollow body (Fig. 6 where the body of 28 is seen) extending therebetween, the elongate body defining a passageway (the passageway seen in Fig. 6 where the component 12 and 26 are inserted into the body 28) extending

from the flared proximal end to the distal end (Fig. 6); and a second component (26) having an elongate body with a tip at a distal end (34), the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 6).

Claim 2: That the passageway includes a first, flared portion (the proximal end is flared as seen in Fig. 6A) extending into a second, tubular portion (the second tubular portion is the passageway that is connected to the flared portion seen in Fig. 6A).

Claims 3 and 11: That the first, flared portion has a curved tapered shape (Fig. 6A). The flared portion is tapered to smoothly connect to the second tubular portion.

Claim 6: That the tip (34) of the second component (26) comprises a spherical tip (Fig. 5 and Col. 4 Lines 12-13).

Claim 8: That the second component (26) further includes at least one sealing ring (48) around the elongate body proximal to the tip (34) as seen in Fig. 6.

Claim 9: An instrument for arthroscopically delivering a tissue scaffold to a damaged or injured tissue site, comprising: an insertion tube (28) having a proximal end, a distal end (Fig. 5 and 6) and a passageway extending therebetween (the passageway seen in Fig. 6 where the component 12 and 26 are inserted into the body 28); and an insertion rod (26) having an elongate shaft (Fig. 5) extending into a handle (42) at a proximal end (Fig. 5) and a blunt tip (34) at a distal end (Fig. 5), the elongate shaft being configured to be removably disposed within the insertion tube for sliding along the passageway and contacting the tissue scaffold (Fig. 6).

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Claim 10: That the passageway includes a first, flared portion (the proximal end is flared as seen in Fig. 6A) extending into a second, tubular portion (the second tubular portion is the passageway that is connected to the flared portion seen in Fig. 6A).

Claim 14: That the proximal end of the insertion tube (28) is flared (30) as seen in Fig. 5.

Claim 16: That the blunt tip (34) of the insertion rod comprises (26) a spherical tip (Fig. 5 and Col. 4 Lines 12-13).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 7, 15, 17, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan et al. (6,328,715).

Claims 4 and 15:

Dragan teaches all the claimed limitations discussed above however, Dragan does not disclose that the flared proximal end of the first component has a diameter in the range of about 15 mm to about 50 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dragan with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

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Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical.

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II).

Claims 7, 17, and 18:

Dragan teaches all the claimed limitations discussed above however, Dragan does not disclose that the spherical tip has a diameter in the range of about 6 mm to about 10 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dragan with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical.

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II).

Claim 19:

Dragan teaches all the claimed limitations discussed above however, Dragan does not disclose that the insertion rod further includes a pair of sealing rings around the elongate body.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have a second sealing ring since the examiner is taking Official Notice that the use of a second sealing ring is well known in the art in order to control the sliding resistance between the first components and the second component as well as providing a seal.

7. Claims 5, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan et al. (6,328,715) in view of Orth et al. (2002/0002360).

Dragan teaches all the claimed limitations discussed above however, Dragan does not disclose that the second, tubular portion has a diameter in the range of about 5 mm to about 17 mm.

Orth discloses that the second, tubular portion (the inner diameter of the cannula 30) has a diameter in the range of about 5 mm to about 17 mm ([0011]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dragan with the diameter range in view of the teachings of Orth in order to have a size similar to the size of the delivery unit or scaffolds that are used in the art.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent De la Torre et al. (5,997,515) discloses a first

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component with a flared proximal end and a second component that slides into the a passageway of the first component.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/Darwin P. Erez/

Primary Examiner, Art Unit 3773